	UNIVERSITY RESEARCH POLICY: Reporting Unanticipated Problems/Adverse Events to the IRB Responsible Office: Research Integrity			
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I. Policy Statement

This policy describes the policy and procedures for reporting unanticipated problems and/or adverse events in IRB-approved/exempt human subjects research projects to the Lehigh University IRB.

II. Reason for Policy

This policy addresses the university's commitment to maintaining an effective, well-functioning, and compliant human research protections program. Federal regulations require institutions engaged in human subjects research to have written procedures for ensuring prompt reporting to the IRB of "unanticipated problems involving risks to subjects or others". In order to ensure that participants are afforded the highest level of protection, the institution applies these reporting requirements to all human subject's research that is the purview of the IRB, regardless of source of funding or applicability of federal regulations.

III. Entities Affected By This Policy

This policy applies to all faculty, staff, and students of the university conducting human subjects research; the IRB committee members and chairs; the Institutional Official (IO); Research Integrity office staff.

IV. Who Should Read This Policy

- Faculty, staff, and students of the university conducting human subjects research subject to IRB review and oversight
- New and re-appointed IRB committee members
- New and re-appointed IRB committee co-chairs
- Research Integrity office staff

V. Web Address For This Policy


[Lehigh University IRB website](#) (IRB Standard Operating Procedures and Policies)

VI. Related Resources

University Policies and Documents
Lehigh University IRB Glossary

VII. Contacts

Subject Matter	Office Name	Telephone Number	E-mail/Web Address
Policy Clarification and Interpretation Requirements or process for reporting	Manager of Research Integrity	610-758-2985	https://research.cc.lehigh.edu/contact-us-0

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Unanticipated Problems			
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VIII. Responsibilities

Responsible Party	List of Responsibilities
Institutional Official (IO) or designee	Receive and assess recommendations from the IRB to suspend the privileges of an investigator or study team member to conduct human subjects research when they are involved in unanticipated problems involving risks to subjects or others and/or serious noncompliance.
IRB committee co-chair	Review and assess unanticipated problem reports per this policy and make appropriate recommendations for further action.
IRB committee member	When unanticipated problem reports are referred for full committee review, participate in the review and assessment of reports per this policy and make appropriate recommendations for further action.
Research Integrity office staff	<p>Receive both initial and formal unanticipated problem reports from investigators.</p> <p>Review reports for completeness and correspond with investigators when additional information is required.</p> <p>Facilitate the IRB co-chair and committee review of unanticipated problem reports and communicate the results of the review to the investigators and others as directed by the IRB.</p> <p>Serve as an informational resource to investigators in determining if and when information is required to be reported per this policy.</p>

IX. Principles

Unanticipated problems are any information that is (1) unanticipated and (2) related or possibly related to participation in research, and (3) indicates that subjects or others are at increased risk of harm. Investigators are required to report the following:

1. Any information that meets all of the following criteria:
 - a. Unanticipated or unexpected, in terms of nature, severity, or frequency, given the research procedures that are described in the protocol-related documents (e.g. the IRB-approved research protocol and informed consent document) and the characteristics of the subject population.
 - b. Related or possibly related to participation in the research (there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research).
 - c. Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.
2. Information that indicates a new or increased risk, or a safety issue. For example:
 - a. New information (e.g. an interim analysis, safety monitoring report, publication in the literature, sponsor report, or investigator finding) that indicates an increase in the frequency or magnitude of a previously known risk, or uncovers a new risk.
 - b. Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol.
 - c. Protocol violation that harmed subjects or others and indicates that subjects or others might be at increased risk of harm.

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- d. Complaint of a subject that indicates subjects or others might be at increased risk of harm or at risk of a new harm.
- e. Any changes significantly affecting the conduct of the research.
3. [Noncompliance](#) with federal regulations governing human research or with the requirements or determinations of the IRB, or an [allegation of such noncompliance](#).
4. Audit, inspection, or inquiry by a federal agency.
5. Written reports of external/sponsor study monitors to the investigator; data safety monitoring board reports; or written reports of sponsors to investigators.
6. Failure to follow the protocol due to the action or inaction of the investigator or research staff.
7. Breach of confidentiality.
8. Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to the subject.
9. Incarceration of a subject in a study not approved by the IRB to involve [prisoners](#).
10. Complaint of a subject that cannot be resolved by the research team.
11. Premature suspension or termination of the research by the sponsor, investigator, this institution, or another institution.

X. Procedures

1. Investigators with IRB-approved/exempt protocols are required to report any of the 11 items above, or information that otherwise qualifies as (1) unanticipated (inconsistent with information previously reviewed by the IRB), (2) related or possibly related to participation in research, and (3) indicates that subjects or others are at increased risk of harm.
2. Initial reports may be made by phone or email and must be made to the [IRB](#) within five business days of the investigator learning of the information.
3. Initial reports must be followed by formal written reports. An Unanticipated Problem Report Form must be submitted as an Unanticipated Problem package in the existing IRBNet project. The report must be submitted within fourteen business days of the investigator learning of the information.
4. The report is reviewed for completeness by the Research Integrity office staff and assigned to the committee co-chairs for initial review.
5. The committee co-chairs assess the report and determine the following:
6. Whether the reported information is an [unanticipated problem involving risks to subjects or others](#).
7. Whether the event could be categorized as [noncompliance](#), in addition to or instead of an unanticipated problem.
8. Whether [suspension of IRB approval](#) or [termination of IRB approval](#) is warranted.
9. Whether further reporting to university officials, federal agencies, and department heads is required.
10. If the reported information is determined to be an [unanticipated problem involving risks to subjects or others](#), the IRB also determines the potential effect on the risks, benefits, and alternatives for subjects as well as whether any additional action is needed. The committee co-chairs may require one or more of the following actions:
 - a. Require modifications to the protocol.
 - b. Require more frequent IRB review of the protocol.
 - c. Require modification of the consent process or documents.
 - d. Requiring the investigator to provide additional information to current and/or past participants or re-consent to participation.
 - e. Requiring additional training of the investigator and/or study staff.
 - f. Reconsideration of IRB approval.
 - g. Implementation of monitoring of the research.
 - h. Implementation of monitoring of the consent process.



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- i. Recommendation to the Institutional Official to suspend the privileges of an investigator or study team member to conduct human subjects research.
 - j. Suspension of the research.
 - k. Termination of the research.
 - l. Refer the report to the full committee.
11. If the reported information is determined not to be an [unanticipated problem involving risks to subjects or others](#), the IRB will not require any further action.